# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| BIGBAND NETWORKS, INC., Plaintiff, | )<br>)<br>) |                       |
|------------------------------------|-------------|-----------------------|
| v.                                 | )<br>)<br>) | C.A. No. 07-351 (JJF) |
| IMAGINE COMMUNICATIONS, INC.,      | )           |                       |
| Defendant.                         | )<br>)      |                       |

# DECLARATION OF KAREN JACOBS LOUDEN IN SUPPORT OF BIGBAND'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR PROTECTIVE ORDER TO STRIKE IMAGINE'S SECOND AMENDED NOTICE OF DEPOSITION OF BIGBAND PURSUANT TO FED. R. CIV. P. 30(B)(6)

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
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Inc.

#### OF COUNSEL:

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May 30, 2008

| IN THE UNITED STATES DISTRICT COURT |
|-------------------------------------|
| FOR THE DISTRICT OF DELAWARE        |

| BIGBAND NETWORKS, INC., Plaintiff, | )<br>)<br>) |
|------------------------------------|-------------|
| V.                                 | )<br>)      |
| IMAGINE COMMUNICATIONS, INC.,      |             |
| Defendant.                         | ,<br>)      |

# DECLARATION OF KAREN JACOBS LOUDEN IN SUPPORT OF BIGBAND'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR PROTECTIVE ORDER TO STRIKE IMAGINE'S SECOND AMENDED NOTICE OF DEPOSITION OF BIGBAND PURSUANT TO FED. R. CIV. P. 30(B)(6)

- I, Karen Jacobs Louden, hereby declare as follows:
- 1. I am a partner with the law firm of Morris, Nichols, Arsht & Tunnell LLP. I am one of the attorneys representing BigBand Networks, Inc. ("Big Band") in this litigation.
- 2. Attached hereto as Exhibit 1 is a true and correct copy of Defendant Impax Laboratories, Inc.'s Second Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6), dated March 9, 2007, in *Wyeth v. Impax Labs., Inc.*, C.A. No. 06-222 (JJF) (D. Del.) (the "Wyeth case").
- 3. Attached hereto as Exhibit 2 is a true and correct copy of an excerpt from the Court's docket in the Wyeth case, reflecting the Court's Oral Order dated March 2, 2007 granting Wyeth's motion for a protective order.
- 4. Attached hereto as Exhibit 3 is a true and correct copy of the Court's April 13, 2007 Memorandum Order in the *Wyeth* case.

- 5. Attached hereto as Exhibit 4 is a true and correct copy of the Court's Order on Defendant's Motion to Compel Wyeth to Produce Properly Prepared Rule 30(b)(6) Witnesses, dated August 15, 2007, in the *Wyeth* case.
- 6. Attached hereto as Exhibit 5 is a true and correct copy of the Court's Order on the disputes and objections related to 30(b)(6) depositions, dated September 5, 2007, in the Wyeth case.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed on this  $30^{th}$  day of May, 2008.

Karen Jacobs Louden (#2881)

#### **CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on May 30, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer MORRIS JAMES LLP

I also certify that copies were caused to be served on May 30, 2008 upon the following in the manner indicated:

## BY HAND AND E-MAIL BY

Mary B. Matterer Morris James LLP 500 Delaware Avenue Suite 1500 Wilmington, DE 19801

## **BY E-MAIL**

John Benassi Alexander Brainerd Heller Ehrman LLP 4350 La Jolla Village Drive Suite 700 San Diego, CA 92122

/s/ Karen Jacobs Louden (#2881)
Karen Jacobs Louden

# EXHIBIT 1

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| WYETH,                    | )     |                              |
|---------------------------|-------|------------------------------|
| Plainti                   | ff,   |                              |
| v.                        | )     | Civil Action No.: 06-222 JJF |
| IMPAX LABORATORIES, INC., | )     |                              |
| Defendar                  | nt. ) |                              |
|                           | )     |                              |

## DEFENDANT IMPAX LABORATORIES, INC.'S SECOND AMENDED NOTICE OF DEPOSITION OF WYETH PURSUANT TO FED. R. CIV. P. 30(B)(6)

PLEASE TAKE NOTICE that commencing at 9:00 a.m. on April 3, 2007 at the offices of Finnegan Henderson Farabow Garrett & Dunner LLP, 901 New York Ave., N.W., Washington, D.C. 20001, or at another mutually agreed upon time and place, Defendant Impax Laboratories, Inc. ("Impax"), through its attorneys, will take the deposition of Plaintiff Wyeth pursuant to Federal Rule of Civil Procedure 30(b)(6). In advance of the deposition, Wyeth shall designate one or more of its directors, officers, managing agents, or other persons who will testify at the deposition on behalf of Wyeth as to all information known or reasonably available to Wyeth regarding the topics set forth in Schedule A hereto and the definitions in Schedule B. In addition, "(1) the deponent must be knowledgeable on the subject matter identified as the area of inquiry, (2) Wyeth must designate more than one deponent if necessary in order to respond to the relevant areas of inquiry specified by Impax, (3) Wyeth must prepare the witness to testify on matters not only known by the deponent, but those that should be known by Wyeth; and (4) Wyeth must substitute an appropriate deponent when it becomes apparent that the previous deponent is unable to respond to certain relevant

areas of inquiry." 7-30 MOORE'S FEDERAL PRACTICE - CIVIL §30.25 (2006) (quoting Alexander v. FBI, 186 F.R.D. 137, 141 (D.D.C. 1998)). The deposition will take place upon oral examination before a notary public or other person authorized to administer oaths, will be recorded by stenographic and/or sound and video means, and will continue from day to day until completed. You are invited to attend and participate.

Dated: March 9, 2007

M. PATRICIA THAYER (pro hac vice) JOHN M. BENASSI (pro hac vice)

JESSICA R. WOLFF (pro hac vice)

DANIEL N. KASSABIAN (pro hac vice)

SAMUEL F. ERNST (pro hac vice)

HELLER EHRMAN LLP

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RICHARD K. HERRMANN (I.D. No. 405) MARY B. MATTERER (I.D. No. 2696) MORRIS JAMES HITCHENS & WILLIAMS LLP 222 Delaware Ave., 10th Floor

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Attorneys for Defendant IMPAX LABORATORIES, INC.

## SCHEDULE A

## DEPOSITION TOPICS

#### I. WYETH'S ALLEGED CONCEPTION AND REDUCTION TO PRACTICE OF THE ALLEGED "INVENTIONS" IN THE PATENTS

- 1. FACTS supporting or evidencing WYETH's conception and reduction to practice of the alleged invention(s) claimed in each of the asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No. 6,274,171 B1. (This should be interpreted to include the identity of documents and witnesses as well as when and where those conceptions and reductions to practice took place, who was present and/or participated, what transpired, what DOCUMENTS were authored contemporaneously or near contemporaneously to record what transpired, and the significance of conception and reduction to practice milestones.)
- 2. Non-privileged information, unless Wyeth knowingly waives privilege, regarding all invention records CONCERNING the asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No. 6,274,171 B1. (This includes without limitation when such records were authored, by whom, pursuant to whose instruction or pursuant to what policy (if any), to whom they were provided, how were they provided, when they were provided, what was the purpose of providing the invention records to such person(s), whether oral communications were contemporaneously or near contemporaneously made with the provision of the records, and where such records are usually kept in the ordinary course of business.)

#### II. **EVOLUTION OF WYETH'S COMMERCIAL PRODUCT --**DEVELOPMENT AND CHARACTERISTICS

FACTS relating to the evolution of the composition and formulations of EFFEXOR XR and the development thereof from June 1990 through July 2002. (This should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where they were developed, who developed them, and what materials and methods were used to develop them). To limit this request further we are acceding to Wyeth's request to not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.

FACTS relating to the in vitro and in vivo release and bioavailability 4. profiles of EFFEXOR XR from June 1990 through July 2002, including target profiles, when and where those profiles were first achieved, who was involved and oversaw this achievement, and what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles. (EFFEXOR XR should be interpreted to include formulations prepared in the development of WYETH'S commercial EFFEXOR XR<sup>TM</sup>, but excluding hydrogel tablets and gelucire capsules.)

#### WYETH'S FAILURES OF OTHER EXTENDED RELEASE III. TECHNOLOGIES WITH VENLAFAXINE

#### A. **Hydrogel Tablets**

- 5. The composition of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in hydrogel tablets, and its development history from June 1990 through March 1996. (These should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where those formulations were developed, who developed them, and what materials and methods were used to develop them.) To limit the request further and acceding to Wyeth's request, this does not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.
- 6. FACTS relating to the *in vitro* and/or *in vivo* release profiles of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in hydrogel tablets, from June 1990 through March 1996. (These should be interpreted to include target profiles, when those profiles were first achieved, who was involved and oversaw this achievement, what materials and methods were used to test and achieve

them, modifications to those release profiles, and difficulties in consistently replicating those profiles.)

#### B. **Gelucire Tablets**

- 7. FACTS relating to the composition of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in Gelucire capsules, and the development thereof from June 1990 through March 1996. (These should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where those formulations were developed, where they were developed, who developed them, and what materials and methods were used to develop them.) To limit the request further and according to WYETH's request this does not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.
- 8. FACTS relating to the in vitro and/or in vivo release profiles of an EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE and Gelucire capsules, from June 1990 through March 1996. (These should be interpreted to include target profiles, when those profiles were first achieved, where they were they achieved, who was involved and oversaw this achievement, what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles.)

#### IV. OTHER EXTENDED RELEASE FORMULATIONS WHICH MIGHT INVALIDATE THE WYETH PATENTS OR RENDER THEM UNENFORCEABLE

#### Alza Art

9. FACTS relating to the composition and intended use of EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE utilizing ALZA's OROS® oral delivery technology, and the historical development thereof from June 1990 through July 2002. (These should be interpreted to include the formulations' intended use by patients, whether the formulations were expected to provide a therapeutic blood plasma

concentration of VENLAFAXINE over a twenty four hour period with diminished incidences of nausea and emesis, whether the formulations were expected to eliminate the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of VENLAFAXINE, modification to the formulations during that period, methods of manufacturing, when those formulations were developed, where they were developed, who developed them, and what materials and methods were used to develop them). To limit this request further we are acceding to Wyeth's request to not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.

10. FACTS relating to the *in vitro* and/or *in vivo* release profiles of an EXTENDED RELEASE FORMULATION by WYETH comprising VENLAFAXINE and utilizing ALZA's OROS<sup>®</sup> oral delivery technology, from June 1990 through July 2002, including target profiles, when those profiles were first achieved, where they were they achieved, who was involved and oversaw this achievement, what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles.

#### B. Propranolol and Other Prior Art

11. WYETH's knowledge of the comparison of the solubility of Propranolol to VENLAFAXINE, studies, tests, trials, research, or experiments conducted from June 1990 through July 2002, that compare chemical properties, including without limitation solubility, of propranolol and its salts, with that of VENLAFAXINE and its salts.

#### V. FACTS EVIDENCING INEQUITABLE CONDUCT BY MISCHARACTERIZING THE CLINICAL STUDIES ON NAUSEA AND FAILURE TO DISCLOSE HIGHLY MATERIAL INFORMATION

12. FACTS showing that the NAMED INVENTORS and persons involved in the prosecution of the PATENTS IN SUIT, were aware of an article by Lynn A. Cunningham, M.D., entitled Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression, published in

volume 9, no. 3 of the Annals of Clinical Psychiatry in 1997 prior to and during the prosecution of the PATENTS IN SUIT.

- 13. The persons at WYETH involved in drafting, reviewing, editing, commenting on, or revising drafts of the article by Lynn A. Cunningham, M.D., entitled Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression, published in volume 9, no. 3 of the Annals of Clinical Psychiatry in 1997, including the titles of, job responsibilities of, and reporting structure surrounding those persons.
- 14. FACTS showing that NAMED INVENTORS and persons involved in the prosecution of the PATENTS IN SUIT, were aware of an article by Richard Entsuah, Ph.D et al, entitled A Benefit Risk Analysis of Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression, published in volume 33, no. 4 of the Psychopharmacology Bulletin in 1997 prior to and during the prosecution of the PATENTS IN SUIT.
- 15. The persons at WYETH involved in drafting, reviewing, editing, commenting on, or revising drafts of the article by Richard Entsuah, Ph.D et al, entitled A Benefit Risk Analysis of Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression, published in volume 33, no. 4 of the Psychopharmacology Bulletin in 1997, including the titles of, job responsibilities of, and reporting structure surrounding those persons.
- 16. FACTS evidencing WYETH's knowledge and research prior to July 2002 demonstrating or refuting that the EXTENDED RELEASE FORMULATION comprising VENLAFAXINE claimed in the PATENTS IN SUIT provided a therapeutic blood plasma concentration of VENLAFAXINE over a twenty-four hour period with diminished incidences of nausea and emesis.
- 17. FACTS evidencing WYETH's knowledge and research prior to July 2002 demonstrating or refuting that the EXTENDED RELEASE FORMULATION comprising

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VENLAFAXINE claimed in the PATENTS IN SUIT eliminated the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of VENLAFAXINE.

#### VI. FACTS SUPPORTING STATEMENTS IN THE PATENTS OR REQUIRED TO UNDERSTAND THEM; AND PATENT PROSECUTION PRACTICE AND RECORDKEEPING

- 18. FACTS supporting examples 1 though 7 of the PATENTS IN SUIT, including without limitation the data and experimental records underlying Examples 1 though 7 and DOCUMENTS evidencing that data and experimental records.
- 19. FACTS supporting tables 1 though 3 of the PATENTS IN SUIT, including without limitation the data underlying Tables 1 through 3 and DOCUMENTS produced by WYETH evidencing that data.
- 20. The support for, the drafting of, the preparation of, and intended meaning of the following passage of the PATENTS IN SUIT:

The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

21. The support for, the drafting of, the preparation of, and the intended meaning of the following passage of the PATENTS IN SUIT:

It was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble.

22. The support for, the drafting of, the preparation of, and intended meaning of the following passage from the Reply Under Rule 111 With Amendment Under

Rule 115 of November 5, 1997 filed with the PTO in U.S. Patent Application, serial no. 08/964,328:

Moreover, there is a tremendous difference in water solubility of the two compounds. The water solubility of propanolol hydrochloride is 93 mg/ml, whereas that of venlafaxine hydrochloride is 574 mg/ml i.e. 6 fold greater.

- WYETH's practices and policies from June 1990 through July 2002 with 23. respect to the prosecution of U.S. patent applications. (This includes the preparation of invention disclosures, evaluation of inventions, performing prior art searches, preparing patent applications, informing inventors of their duty of candor to the Patent Office, gathering and submitting prior art during the course of patent prosecution, evaluation of U.S. Patent and Trademark Office actions and examiner amendments, drafting and review of responses to Office actions, decisions to file provisional, continuation or continuation-in-part applications, and decisions to abandon applications.)
- WYETH's procedures for collecting and maintaining DOCUMENTS 24. and/or THINGS in their central files, archival or storage locations, and/or kept by individual employees. (This includes without limitation how the DOCUMENTS are organized in central files and/or archival or storage locations, the criteria for whose DOCUMENTS should be or were collected, and what measures are or were taken to ensure that all relevant documents are or were collected in response to requests for DOCUMENTS and THINGS propounded by IMPAX in this action and the defendants in Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey.)
- 25. FACTS and DOCUMENTS CONCERNING the affirmative statements and denials in paragraphs 67 and 68 of WYETH'S REPLY.

### WYETH'S NEW DRUG APPLICATION (NDA) AND STATEMENTS MADE TO THE FDA THAT CONTRADICT THE PATENTS AND WYETH'S INTERPRETATION OF THE CLAIMS

- FACTS evidencing the following parts and contents of NDA No. 20-699 including without limitation any amendments thereto through July 2002:
  - (a) Integrated Safety Summary
  - Summary of Human and Pharmacokinetics and Bioavailability
- The passage with respect to 600B-144FR stating that that there was (c) "a dissociation between peak venlafaxine concentration and peak nausea. In all treatment conditions the maximum nauseating effect occurred before the time of peak concentration . . . . Compared with venlafaxine CF, the ER formulation, which reached comparable levels with a delayed tmax produced a much less intense maximum effect and a decrease of 63% in the area under the concentration-time curve (AUC) of nausea normalized by dose."
- The passage with respect to 600B-144FR stating that that there was (d) "The incidence and severity of nausea would be expected to be less with venlafaxine ER than venlafaxine IR. This conclusion is based on the results of the study 600B-144FR...The incidence of nausea as an adverse event and the severity of nausea, measured as the AUC for a visual analog scale, where lower with venlafaxine ER administration than with venlafaxine IR administration."

### VIII. THE ALLEGED COMMERCIAL SUCCESS BY WYETH IS NOT ATTRIBUTABLE TO THE ALLEGED INVENTION BUT TO ADVERTISING AND PROMOTION

#### A. Advertising, pricing and marketing

- For the years 1997 through the second quarter of 2006, causes in any 27. fluctuations of, and strategies to maintain or increase, the market share of EFFEXOR XR in the United States.
- 28. For the years 1997 through the second quarter of 2006, advertising budgets and the content and effectiveness of any advertising and promotional plans and

efforts for EFFEXOR XR in the United States, including without limitation detailing, sampling, and print, radio, and television advertisements, the size of the marketing and sales force, yearly advertising budgets and expenditures.

- 29. For the years December 2005 to the present, strategies to shift or switch the subscription and/or the consumption of EFFEXOR XR to desvenlafaxine succinate, to be marketed as Pristiq or as another brand name in the United States. (This includes any expected changes in market share of EFFEXOR XR, and any planned print, radio, and television advertisements, the preparation marketing force, rebates, discounts, or changes in pricing pursuant to such strategies.)
- 30. For the years 1994 through 1998, the content and effectiveness of any advertising and promotional efforts for EFFEXOR in the United States, including without limitation detailing, sampling, and print, radio, and television advertisements, the size of the marketing and sales force, yearly advertising budgets and expenditures.
- 31. All correspondence with its advertising agencies involved in advertising EFFEXOR and EFFEXOR XR.

#### B. Revenue, expenses and profitability

32. Revenue, expenses, and profitability for the years 1997 through the second quarter of 2006 from the sale of EFFEXOR XR in the United States, including without sales projections, actual sales, market shares, and profit margins;

Filed 05/30/2008

## DEFINITIONS FOR DEPOSITION TOPICS

When used in the following deposition topics, the following definitions apply:

- 1. "WYETH" means Plaintiff Wyeth and that company as it was previously named and any related companies, parents, divisions, or subsidiaries, past or present, located in the U.S. or abroad, and the past or present directors, officers, employees, agents, representatives or attorneys thereof.
- 2. "IMPAX" means Defendant IMPAX Laboratories, Inc. and its past or present directors, officers, employees, agents, representatives or attorneys known to WYETH.
- 3. "CONCERNING" means referring to, relating to, regarding, comprising, constituting, containing, demonstrating, describing, discussing, evidencing, evincing, evidencing, indicating, on the subject of, on the topic of, showing, or prepared in connection with the stated matter.
- "DATE" means the exact day, month, and year, if so ascertainable, or if 4. not, the best approximation (including relationship to other events).
- "DOCUMENT" or "DOCUMENTS" means all written, printed, typed, electronically produced, electronically stored, photostatic, photographed, recorded, or otherwise reproduced communications or records of every kind and description, whether comprised of letters, words, pictures, sounds, symbols, or combinations thereof. DOCUMENTS include originals as well as drafts, copies, marked-up copies, non-identical duplicates, and computer files, including backup or archival copies.
- 6. "THING" or "THINGS" means any tangible item, including without limitation models, prototypes, research models or samples, and samples of any device or apparatus, or product.

- 7. "FACTS" includes all evidence including documents concerning thereof, and witnesses knowledgeable of the same.
- 8. "PERSON" means any natural person, firm, association, organization, partnership, business, trust, corporation, or public entity.
  - 9. "PTO" means the United States Patent and Trademark Office.
  - 10. "FDA" means the United States Food and Drug Administration.
  - 11. "NDA" means New Drug Application.
  - 12. "ANDA" means Abbreviated New Drug Application.
  - 13. "VENLAFAXINE" means the compound
- 1-[(2-dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol commonly known as venlafaxine, as well as all compositions, formulations, and preparations containing venlafaxine, including without limitation VENLAFAXINE and other pharmaceutically acceptable salts of venlafaxine.
- 14. "EFFEXOR" means the VENLAFAXINE product sold by WYETH as Effexor®.
- 15. "EFFEXOR XR" means the VENLAFAXINE product sold by WYETH as Effexor® XR.
- 16. "PATENTS IN SUIT" means U.S. Patent No. 6,274,171 B1, U.S. Patent No. 6,403,120 B1, U.S. Patent No. 6,419,958 B2, and any other patent asserted by WYETH as infringed by IMPAX in the above-captioned action, individually or collectively.
- 17. "NAMED INVENTORS" means Deborah M. Sherman, John C. Clark, John U. Lamer, Steven A. White, and any other person listed as an inventor for the PATENTS IN SUIT, individually or collectively.
- 18. For the purposes of this notice only, "EXTENDED RELEASE FORMULATION" means a formulation which releases the active ingredient at a slower

### CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2007, the foregoing document, DEFENDANT IMPAX LABORATORIES, INC.'S SECOND AMENDED NOTICE OF DEPOSITION OF WYETH PURSUANT TO FED. R. CIV. P. 30(b)(6), was served on counsel via U.S. Mail:

Jack B. Blumenfeld Karen Jacobs Louden Morris Nichols Arsht & Tunnell 1201 N. Market Street Wilmington, DE 19801

Basil J. Lewris Linda A. Wadler Finnegan Henderson Farabow Garrett & Dunner 901 New York Avenue, N.W. Washington, DC 20001

Dated: March 9, 2007

M. PATRICIA THAYER (pro hac vice) JOHN M. BENASSI (pro hac vice) JESSICA R. WOLFF (pro hac vice) SAMUEL F. ERNST (pro hac vice)

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MARY B. MATTERER (I.D. No. 2696)

MORRIS JAMES HITCHENS & WILLIAMS LLP

222 Delaware Ave., 10th Floor

Wilmington, DE 19801 Telephone: (302) 888-6800

Attorneys for Defendant

IMPAX LABORATORIES, INC.

#### PROOF OF SERVICE BY MAIL

I, Francesca Romero, declare as follows:

I am employed with the law firm of Heller Ehrman LLP, whose address is 4350 La Jolla Village Drive, 7th Floor, San Diego, California 92122. I am readily familiar with the business practices of this office for collection and processing of correspondence for mailing with the United States Postal Service; I am over the age of eighteen years and not a party to this action.

On March 9, 2007, I served the following:

## DEFENDANT IMPAX LABORATORIES, INC.'S SECOND AMENDED NOTICE OF DEPOSITION OF WYETH PURSUANT TO FED. R. CIV. P. 30(B)(6)

on the below parties in this action by placing true copies thereof in sealed envelopes, addressed as shown, for collection and mailing pursuant to the ordinary business practice of this office, which is that correspondence for mailing is collected and deposited with the United States Postal Service on the same day in the ordinary course of business:

Linda A. Wadler, Esq. Finnegan Henderson Farabow Garrett & Dunner LLP 901 New York Avenue, N.W. Washington, DC 20001-4413 Jack B. Blumenfeld, Esq. Morris, Nichols, Arsht & Tunnell 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899-1347

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this Proof of Service was executed on March 9, 2007 in San Diego, California.

# EXHIBIT 2

PATENT, PaperDocuments

# U.S. District Court District of Delaware (Wilmington) CIVIL DOCKET FOR CASE #: 1:06-cy-00222-J.JF

Wyeth v. Impax Laboratories Inc. Assigned to: Judge Joseph J. Farnan, Jr. Cause: 35:271 Patent Infringement

Date Filed: 04/05/2006 Jury Demand: None Nature of Suit: 830 Patent Jurisdiction: Federal Question

#### **Plaintiff**

Wyeth

## represented by Jack B. Blumenfeld

Morris, Nichols, Arsht & Tunnell LLP 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899 (302) 658-9200 Email: jbbefiling@mnat.com LEAD ATTORNEY ATTORNEY TO BE NOTICED

#### Melissa Stone Myers

Melissa Stone Myers, Esq. 6125 Mordred Lane Austin, TX 78739 (512-215-2377 Email: mmyers99@austin.rr.com TERMINATED: 09/27/2006 LEAD ATTORNEY ATTORNEY TO BE NOTICED

#### Karen Jacobs Louden

Morris, Nichols, Arsht & Tunnell 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899 (302)658-9200 Email: kjlefiling@mnat.com ATTORNEY TO BE NOTICED

V.

#### Defendant

Impax Laboratories Inc.

represented by Mary Matterer
Morris James LLP

Filed 05/30/2008

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500 Delaware Avenue, Suite 1500 P.O. Box 2306 Wilmington, DE 19899-2306 (302) 888-6800 Fax: (302) 571-1750 Email: mmatterer@morrisjames.com LEAD ATTORNEY ATTORNEY TO BE NOTICED

#### Daniel N. Kassabian

Pro Hac Vice Email: daniel.kassabian@hellerehrman.com ATTORNEY TO BE NOTICED

## Joseph C. Gratz

Pro Hac Vice Email: wyeth-kvn@kvn.com ATTORNEY TO BE NOTICED

#### Samuel Ernst

Pro Hac Vice Email: sam.ernst@hellerehrman.com TERMINATED: 10/15/2007 ATTORNEY TO BE NOTICED

#### **Counter Claimant**

Impax Laboratories Inc.

represented by Mary Matterer

(See above for address)

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

V.

**Counter Defendant** 

Wyeth

represented by Karen Jacobs Louden

(See above for address)
ATTORNEY TO BE NOTICED

**Counter Claimant** 

Impax Laboratories Inc.

V.

**Counter Defendant** 

Wyeth

represented by Jack B. Blumenfeld

(See above for address)

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Melissa Stone Myers

(See above for address)
TERMINATED: 09/27/2006
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

## Karen Jacobs Louden

(See above for address)
ATTORNEY TO BE NOTICED

| Date Filed | #        | Docket Text  |
|------------|----------|--|
| 04/05/2006 | 1        | COMPLAINT filed against Impax Laboratories Inc Magistrate Consent Notice to Pltf. (Filing fee \$ 250, receipt number 142980.) - filed by Wyeth. (Attachments: # 1 Exhibit A-C# 2 Civil Cover Sheet # 3 Acknowledgement of Consent Form)(bad, ) (Entered: 04/06/2006) |
| 04/05/2006 |          | Summons Issued as to Impax Laboratories Inc. on 4/5/2006. (bad, ) (Entered: 04/06/2006)  |
| 04/05/2006 | 2        | Disclosure Statement pursuant to Rule 7.1 filed by Wyeth. (bad, ) (Entered: 04/06/2006)  |
| 04/05/2006 | 3        | Notice of Availability of a U.S. Magistrate Judge to Exercise Jurisdiction (bad, ) (Entered: 04/06/2006)   |
| 04/06/2006 | 4        | Report to the Commissioner of Patents and Trademarks for Patent Number(s) 6,274,171; 6,403,120; 6,419,958; (bad, ) (Entered: 04/06/2006)   |
| 04/06/2006 | <u>5</u> | Return of Service Executed by Wyeth. Impax Laboratories Inc. served on 4/5/2006, answer due 4/25/2006. (Blumenfeld, Jack) (Entered: 04/06/2006)  |
| 04/12/2006 |          | Case assigned to Judge Joseph J. Farnan, Jr. Please include the initials of the Judge (JJF) after the case number on all documents filed. (rjb, ) (Entered: 04/12/2006)  |
| 04/20/2006 | 6        | MOTION for Pro Hac Vice Appearance of Attorney Basil J. Lewris, Linda A. Wadler - filed by Wyeth. (Blumenfeld, Jack) (Entered: 04/20/2006)   |
| 04/24/2006 |          | SO ORDERED, re 6 MOTION for Pro Hac Vice Appearance of Attorney Basil J. Lewris, Linda A. Wadler filed by Wyeth . Signed by Judge Joseph J. Farnan, Jr. on 04/24/06. (afb, ) (Entered: 04/24/2006)   |
| 04/25/2006 | 7        | ANSWER to Complaint with Jury Demand, COUNTERCLAIM against Wyeth by Impax Laboratories Inc(Matterer, Mary) (Entered: 04/25/2006)   |
| 04/25/2006 | 8        | Disclosure Statement pursuant to Rule 7.1 filed by Impax Laboratories Inc (Matterer, Mary) (Entered: 04/25/2006)   |
| 05/12/2006 | 9        | MOTION to Strike 7 Answer to Complaint, Counterclaim Wyeth's Motion To Strike Impax's Unenforceability And Unclean Hands Affirmative Defenses Under Fed. R. Civ. P. 12(f), And To Dismiss Impax's Unenforceability   |

|            |    | Order to Strike and Limit the Scope of Impax's Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6) filed by Impax Laboratories IncReply Brief due date per Local Rules is 3/5/2007. (Herrmann, Richard) (Entered: 02/21/2007)  |
|------------|----|---|
| 02/27/2007 | 91 | MOTION for Pro Hac Vice Appearance of Attorney Alan A. Wright - filed by Wyeth. (Blumenfeld, Jack) (Entered: 02/27/2007)  |
| 02/27/2007 | 92 | NOTICE OF SERVICE of Impax's Fourth Set of Requests for Production (Nos. 125-131) and First Set of Requests for Admission (Nos. 1-6) by Impax Laboratories Inc(Herrmann, Richard) (Entered: 02/27/2007)   |
| 02/28/2007 | 93 | SEALED REPLY BRIEF re 76 MOTION to Compel A Response to Interrogatory No. 35 Defendant's Reply Brief In Support of Motion To Compel A Response to Interrogatory Number 35 filed by Impax Laboratories Inc (Herrmann, Richard) (Entered: 02/28/2007)   |
| 02/28/2007 | 94 | DECLARATION re <u>93</u> Reply Brief Declaration of Mary B. Matterer In Further Support of Defendant's Motion to Compel a Response to Interrogatory Number 35 by Impax Laboratories Inc (Herrmann, Richard) (Entered: 02/28/2007)   |
| 02/28/2007 | 95 | REDACTED VERSION of <u>88</u> Answering Brief in Opposition to Impax's Motion to Compel a Response to Interrogatory Number 35 by Wyeth. (Louden, Karen) (Entered: 02/28/2007)   |
| 02/28/2007 | 96 | REDACTED VERSION of 89 Declaration of Karen Jacobs Louden in Support of Wyeth's Opposition to Impax's Motion to Compel a Response to Interrogatory Number 35 by Wyeth. (Louden, Karen) (Entered: 02/28/2007)  |
| 02/28/2007 | 97 | SEALED REPLY BRIEF re <u>81</u> MOTION for Protective Order to Strike and Limit the Scope of Impax's Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6) filed by Wyeth. (Louden, Karen) (Entered: 02/28/2007)   |
| 02/28/2007 | 98 | SEALED DECLARATION re <u>97</u> Reply Brief of Karen Jacobs Louden in Support of Wyeth's Reply in Support of its Motion for Protective Order by Wyeth. (Attachments: # <u>1</u> Exhibits 13 through 16)(Louden, Karen) (Entered: 02/28/2007)  |
| 03/01/2007 | 99 | REDACTED VERSION of <u>90</u> Answering Brief in Opposition, Redacted Version of Impax's Opposition to Plaintiff Wyeth's Motion for Protective Order To Strike and Limit the Scope of Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6) by Impax Laboratories Inc (Attachments: # 1 Exhibit A-Y)(Matterer, Mary) (Entered: 03/01/2007) |
| 03/01/2007 |    | SO ORDERED D.I. 91 MOTION for Pro Hac Vice Appearance of Attorney Alan A. Wright filed by Wyeth. Signed by Judge Joseph J. Farnan, Jr. on 3/1/2007. (lec) (Entered: 03/02/2007)   |
| 03/02/2007 |    | ORAL ORDER: For the reasons stated on the record during the 3/2/07 Motion day Hearing, D.I. <u>76</u> MOTION to Compel <i>A Response to Interrogatory No. 35</i> filed by Impax Laboratories Inc. is GRANTED; D.I. <u>81</u> MOTION for Protective Order <i>to Strike and Limit the Scope of Impax's Amended Notice of</i>                                      |

|            |     | Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6) filed by Wyeth is GRANTED. Ordered by Judge Joseph J. Farnan, Jr. on 03/02/2007. (dlk) (Entered: 03/02/2007)   |
|------------|-----|---|
| 03/02/2007 |     | Minute Entry for proceedings held before Judge Joseph J. Farnan, Jr.: Motion Day Hearing held on 3/2/2007. re D.I. <u>81</u> and D.I. <u>76</u> . Oral Order issued. (Court Reporter Heather M. Triozzi.) (lec) (Entered: 03/06/2007)                         |
| 03/05/2007 | 100 | REDACTED VERSION of <u>97</u> Reply Brief <i>REDACTED/Wyeth's Reply Brief In Support Of Its Motion For Protective Order</i> by Wyeth. (Louden, Karen) (Entered: 03/05/2007)   |
| 03/05/2007 | 101 | REDACTED VERSION of <u>98</u> Declaration <i>REDACTED/Declaration Of Karen Jacobs Louden In Support Of Wyeth's Reply In Support Of Its Motion For Protective Order</i> by Wyeth. (Attachments: # <u>1</u> Exhibit 13-16)(Louden, Karen) (Entered: 03/05/2007) |
| 03/06/2007 | 106 | TRANSCRIPT of Motion Hearing held on 3/2/2007 before Judge Joseph J. Farnan, Jr. Court Reporter: Heather M. Triozzi. (Transcript on file in Clerk's Office) (lec) (Entered: 03/07/2007)   |
| 03/07/2007 | 102 | NOTICE to Take Deposition of Charles Hsiao on March 23, 2007 by Wyeth. (Louden, Karen) (Entered: 03/07/2007)  |
| 03/07/2007 | 103 | NOTICE to Take Deposition of Christina Leung on March 22, 2007 by Wyeth.(Louden, Karen) (Entered: 03/07/2007)   |
| 03/07/2007 | 104 | NOTICE to Take Deposition of John C. Clark on April 11, 2007 by Impax Laboratories Inc(Matterer, Mary) (Entered: 03/07/2007)  |
| 03/07/2007 | 105 | NOTICE to Take Deposition of Deborah M. Sherman on April 10, 2007 by Impax Laboratories Inc(Matterer, Mary) (Entered: 03/07/2007)   |
| 03/07/2007 | 107 | REDACTED VERSION of 93 Reply Brief Redacted Version of Defendant's Reply Brief in Support of Motion to Compel a Response to Interrogatory Number 35 by Impax Laboratories Inc (Matterer, Mary) (Entered: 03/07/2007)  |
| 03/12/2007 | 108 | NOTICE OF SERVICE of Response and Objections of Lynn A. Cunningham, M.D. to Subpoena by Wyeth.(Louden, Karen) (Entered: 03/12/2007)   |
| 03/14/2007 | 109 | NOTICE OF SERVICE of Impax's Second Set of Requests For Admission (Nos. 7-73) by Impax Laboratories Inc(Matterer, Mary) (Entered: 03/14/2007)   |
| 03/16/2007 | 110 | NOTICE OF SERVICE of Impax's Second Amended Notice of Deposition to Wyeth by Impax Laboratories Inc(Matterer, Mary) (Entered: 03/16/2007)   |
| 03/16/2007 | 111 | NOTICE of Motion to Compel by Impax Laboratories Inc. (Matterer, Mary) (Entered: 03/16/2007)  |
| 03/16/2007 | 112 | MOTION to Compel <i>Deposition Pursuant to Fed. R. Civ. P. 30(b)(6)</i> - filed by Impax Laboratories Inc (Matterer, Mary) (Entered: 03/16/2007)  |
| 03/16/2007 | 113 | SEALED OPENING BRIEF in Support re 112 MOTION to Compel   |

# EXHIBIT 3

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH, :

Plaintiff, :

v. : Civil Action No. 06-222-JJF

.

IMPAX LABORATORIES, INC.,

:

Defendant.

#### MEMORANDUM ORDER

Pending before me is Defendant Impax Laboratories, Inc.'s ("Impax") Motion To Compel Deposition Pursuant To Fed. R. Civ. P. 30(b)(6). (D.I. 112). Two factors convince me that the Motion as currently presented should be granted.

First, I am persuaded by Impax's argument that the proposed deposition is the most efficient way to proceed (D.I. 113, p. 15). I note that my conclusion is influenced by the <u>Teva</u> factors raised by Impax. Second, the time limitations offered by Impax will control any "unduly burdensome" concerns raised by Wyeth.

NOW THEREFORE, IT IS HEREBY ORDERED that Defendant's Motion to Compel Deposition Pursuant To Fed. R. Civ. P. 30(b)(6). (D.I. 112) is **GRANTED**.

April 13, 2007

UNITED STATES DISTRICT JUDGE

# EXHIBIT 4

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| WYETH, Plaintiff,         |                               |
|---------------------------|-------------------------------|
| v.                        | Civil Action No. 06-222 (JJF) |
| IMPAX LABORATORIES, INC., | {                             |
| Defendant.                | }                             |

# ORDER ON DEFENDANT'S MOTION TO COMPEL WYETH TO PRODUCE PROPERLY PREPARED RULE 30(b)(6) WITNESSES

The Court having considered the parties' submissions regarding Defendant Impax Laboratories, Inc.'s Motion to Compel Wyeth To Produce Properly Prepared Rule 30(b)(6) Witnesses, (D.I. 207), the Court has granted the Motion with specificity at the July 13, 2007 motion hearing. The following procedures shall apply:

- 1. On or before July 20, 2007, Defendant shall file a revised notice that identifies subtopics for which it seeks additional testimony, only with respect to Topics 3 through 8, 10 (in vivo testing only), 16, 17, 19 (Tables 2 and 3 only), 20, 25, and 26 of its April 3, 2007 Second Amended Notice of Deposition Pursuant to Rule 30(b)(6). The notice shall contain narrowed subtopics and relate the noticed subtopics to an issue in the case and narratively explain why the noticed subtopic would be probative in some substantial way to an issue in the case. Impax should attempt to have as narrow a notice as possible. Wyeth shall serve its objections to the noticed subtopics on or before July 25, 2007.
- The parties shall meet and confer regarding the identified subtopics and objections on July 26, 2007.
- On or before July 31, 2007, the parties shall file a joint chart containing the subtopics, the narrative explanations, and remaining objections.

- The Court will rule on the objections prior to the deposition without further briefing from the Parties.
- Wyeth shall identify the witnesses it intends to designate to testify regarding the identified subtopics.
- The 30(b)(6) deposition of Plaintiff shall take place on September 5 and 11, 2007
   Courtroom No. 4B of J. Caleb Boggs Federal Building, 844 N. King Street, Wilmington,
   Delaware beginning at 9:00 a.m.

#### AGREED AS TO FORM:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP MORRIS JAMES LLP

/s/ Karen Jacobs Louden

Jack B. Blumenfeld (#1014) Karen Jacobs Louden (#2881) 1201 N. Market Street Wilmington, DE 19899-1347 (302) 658-9200 Attorneys for Plaintiff

#### OF COUNSEL:

Basil J. Lewris
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/s/ Mary B. Matterer

Mary B. Matterer (#2696) 500 Delaware Avenue Suite 1500 P.O. Box 2306 Wilmington, DE 19899 Attorneys for Defendant

#### OF COUNSEL:

Daralyn J. Durie Asim Bhansali Paula. L. Blizzard Joseph C. Gratz Keker & Van Next LLP 710 Sansome Street San Francisco, CA 94111 (415) 391-5400

IT IS SO ORDERED this \_\_\_\_/5\_ day of July, 2007.

United States District Court Judge

# EXHIBIT 5

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v. : Civil Action No. 06-222-JJF

IMPAX LABORATORIES, INC.,

Defendant.

#### ORDER

IT IS HEREBY ORDERED that disputes and objections related to 30(b)(6) depositions scheduled for September 5 and 11, 2007 are resolved as follows:

- 1. Designation B 3
  - The Objections of Wyeth are **SUSTAINED** and its Proposal for the topics is **ADOPTED**.
- 2. Designation D 3, 5, 7
  The objections of Wyeth are <u>SUSTAINED</u> and its
  Proposal for the topics is **ADOPTED**.
- Designation Q 16, 17, 20
   The objections of Wyeth are OVERRULED.
- 4. Designation R 10
  The objections of Wyeth are <u>OVERRULED</u>.

September 5, 2007

NITED STATES DISTRICT JUDGE